UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,018	02/20/2002	Li How Chen	10275-133002 / GTC-39C US	8070

26161 7590 03/10/2004

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
PARAS JR, PETER	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/082,018	CHEN ET AL.	
	Examiner	Art Unit	
	Peter Paras, Jr.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-84* is/are pending in the application.

4a) Of the above claim(s) *77-84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _____ is/are rejected.

7)☐ Claim(s) *9-76* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0202, 0602*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: _____. Notice to Comply

DETAILED ACTION

Claims 9-84 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 9-76, drawn to methods of producing merozoite surface protein 1 (MSP-1) in the milk of a transgenic non-human mammal and transgenic non-human mammals that express MSP-1 in milk, classified in classes 800 and 800, subclasses 4 and 14.

II. Claims 77-84, drawn to an MSP-1 protein, classified in classes 530 and 530, subclasses 822 and 350.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the method can be extrapolated to the production of other proteins in the milk of transgenic non-human mammals and the product, the MSP-1 protein, can be produced by a materially different process, such as in a cell culture system. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate classification, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result**

in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Byron Olsen on 2/12/04 a provisional election was made without traverse to prosecute the invention of Group I, claims 9-76. Affirmation of this election must be made by applicant in replying to this Office action. Claims 77-84 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached **N**otice To Comply With Requirements For Patent Applications Containing **N**ucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicants are required to comply with all of the requirements of 37 C.F.R. §§ 1.821 through 1.825. *Any* response to this Office Action, which fails to meet all of these requirements, will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. §§ 1.821 through 1.825 did not preclude the examination of the application on the merits, the results of which are communicated below.

Priority

Applicants should amend the first line of the specification to update the status of parent applications.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. The preliminary amendment to the first line of the specification filed on 2/20/04 inadvertently states the instant application is continuation of parent application 09/175,984. Since, there was a restriction in the parent application in which transgenic non-human mammals were separated into a different group from nucleic acids, the

instant application would be more accurately classified as a divisional application of 09/175,684.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to methods of producing MSP-1 in the milk of a transgenic non-human mammal. The claims are further directed to transgenic non-human mammals that produce MSP-1 in their milk.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

The specification has provided a description for the nucleic acid sequence set forth in SEQ ID NO: 2, which encodes a wild-type merozoite surface protein 1 (MSP-1). The specification has provided a description for the following modifications of the nucleic acid sequence set forth in SEQ ID NO: 2: a) a modified nucleotide sequence of SEQ ID NO: 2 such that the AT content is reduced to 50% or less by replacing wild-type codons with mammary gland preferred codons encoding the same amino acid as the replaced codon; b) a modified nucleotide sequence of SEQ ID NO: 2 such that the AT content is reduced to 50% or less by replacing wild-type codons with mammary gland preferred codons, wherein at least one glycosylation site of SEQ ID NO: 10 has been altered such that it is not functional, and wherein the altered glycosylation sites are at positions 182 and 263 of SEQ ID NO: 10; c) a modified nucleotide sequence of SEQ ID NO: 2 such that all the mRNA instability motifs have been eliminated by replacing wild-type codons with mammary gland preferred codons encoding the same amino acid as the replaced codon; and d) a modified nucleotide sequence of SEQ ID NO: 2 such that all the mRNA instability motifs have been eliminated by replacing wild-type codons with mammary gland preferred codons encoding the same amino acid as the replaced codon, wherein at least one glycosylation site of SEQ ID NO: 10 has been altered such that it is not functional, and wherein the altered glycosylation sites are at positions 182 and 263 of SEQ ID NO: 10. The specification has not provided a description for all other nucleotide sequences encoding MSP-1, including fragments thereof, as embraced by the claims.

Based upon the prior art there is expected to be sequence variation among the species of cDNA, which encode MSP-1. There is no evidence on the record of a relationship between the structures of the DNA molecules encoding any MSP-1 that would provide any reliable information about the structure of DNA molecules within the genus. There is no evidence on the record that the encompassed nucleic acid molecules had known structural relationships to each other; the art indicated that there is variation between DNA sequences encoding MSP-1. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case the other nucleotide sequences encoding MSP-1, including fragments thereof, as embraced by the claims within the genus of MSP-1 encoding nucleic acid molecules lack a written description. The specification fails to describe what DNA molecules fall into this genus. The skilled artisan cannot envision the detailed chemical structure of the encompassed DNA molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a

potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus of nucleic acid molecules encoding MSP-1. Moreover, the art has recognized that there would be variation among the species of the genus of DNA molecules that encode MSP-1. Therefore, Applicant was not in possession of the genus of DNA molecules that encode MSP-1 as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claims 9-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to methods of producing MSP-1 in the milk of a transgenic non-human mammal. The claims are further directed to transgenic non-human mammals that produce MSP-1 in their milk.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

The transgenic non-human mammals, other than a mouse, whose genomes comprise nucleotide sequences encoding merozoite surface protein 1(MSP-1), wherein MSP-1 is expressed in milk embraced by the claims have not been disclosed. There is no evidence on the record of a relationship between the structures of the transgenic non-human mammals embraced by the claims that would provide any reliable information about the structure of the transgenic non-human mammals within the genus. There is no evidence on the record that the transgenic non-human mammals embraced by the claims had known structural relationships to each other. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not

conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998).

In the instant case the claimed embodiments of transgenic non-human mammals, other than a transgenic mouse, whose genomes comprise nucleotide sequences encoding MSP-1, wherein MSP-1 is expressed in milk, within the genus lack a written description. The specification fails to describe what transgenic non-human mammals, other than a mouse, fall into this genus and it was unknown as of Applicant's effective filing date that any of these transgenic non-human mammals, other than mouse, would have the property of expressing MSP-1 in milk. The skilled artisan cannot envision the detailed chemical structure of the encompassed transgenic non-human mammals, and therefore conception is not achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of the above considerations one of skill in the art would not recognize that applicant was in possession of the necessary common features or attributes possessed by member of the genus of transgenic non-human mammals, other than mouse, whose genomes comprise a nucleotide sequence encoding MSP-1, wherein MSp-1 is expressed in milk. The described transgenic mouse is not representative of the claimed genus of transgenic non-human mammals. Therefore, Applicant was not in possession of the genus of transgenic non-human mammals as encompassed by the claims. University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that to fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention."

Claims 9-76 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods and transgenic non-human mammals with to the extent of a transgenic mouse whose genome comprises a modified nucleotide sequence, of the nucleotide sequence set forth in SEQ ID NO: 2, encoding a merozoite surface protein 1 (MSP-1) operably linked to a mammary gland specific promoter, wherein the modified nucleotide sequences of SEQ ID NO: 2 are as follows: a) a modified nucleotide sequence of SEQ ID NO: 2 such that the AT content is reduced to 50% or less by replacing wild-type codons with mammary gland preferred

codons encoding the same amino acid as the replaced codon; b) a modified nucleotide sequence of SEQ ID NO: 2 such that the AT content is reduced to 50% or less by replacing wild-type codons with mammary gland preferred codons, wherein at least one glycosylation site of SEQ ID NO: 10 has been altered such that it is not functional, and wherein the altered glycosylation sites are at positions 182 and 263 of SEQ ID NO: 10; c) a modified nucleotide sequence of SEQ ID NO: 2 such that all the mRNA instability motifs have been eliminated by replacing wild-type codons with mammary gland preferred codons encoding the same amino acid as the replaced codon; and d) a modified nucleotide sequence of SEQ ID NO: 2 such that all the mRNA instability motifs have been eliminated by replacing wild-type codons with mammary gland preferred codons encoding the same amino acid as the replaced codon, wherein at least one glycosylation site of SEQ ID NO: 10 has been altered such that it is not functional, and wherein the altered glycosylation sites are at positions 182 and 263 of SEQ ID NO: 10, does not reasonably provide enablement all other transgenic non-human mammals and nucleotide sequences embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are directed to methods of producing MSP-1 in the milk of a transgenic non-human mammal. The claims are further directed to transgenic non-human mammals that produce MSP-1 in their milk.

The specification discusses that the invention features methods of producing modified MSP-1 in the milk of transgenic non-human mammals. The specification

discusses that the invention features modifications of the nucleotide sequence set forth in SEQ ID NO: 2, which encode MSP-1, wherein the modified nucleotide sequences are expressed more efficiently in the milk of a transgenic non-human mammal. While the specification provides extensive teachings pertaining to the creation and use of a transgenic mouse as per the enabled scope set forth above the specification fails to provide any relevant teachings or specific guidance with regard to the creation and use of the other transgenic non-human mammals embraced by the claims. Given the lack of guidance provided by the specification it would have required undue experimentation to practice the claimed invention with the other transgenic non-human mammals embraced by the claims.

While the specification has provided guidance for the creation and use of a transgenic mouse as per the enabled scope set forth above, the specification has not provided relevant teachings or guidance for the other transgenic non-human mammals embraced by the claims. The specification has contemplated that other transgenic non-human mammals could be created. See the specification on page 8. However, the specification has failed to recite which other transgenic non-human mammals could be created in accordance with the claimed invention. Moreover, the specification has failed to provide any guidance, working examples, or relevant teachings that would allow the skilled artisan to create the other transgenic non-human mammals embraced by the claims when practicing the claimed invention and the specification has not provided any correlation between the exemplified transgenic mouse and the other transgenic non-human mammals embraced by the claims so that the skilled artisan could extrapolate

the transgenic mouse to other transgenic non-human mammals. As previously stated the specification has not even identified which other transgenic non-human mammals could be used to practice the claimed invention. A mere statement that other transgenic non-human mammals could be created and used is not sufficient to enable the breadth of the claimed as directed to any transgenic non-human mammal. If there is no disclosure of starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art. See Genentech Inc. v. Novo Nordisk A/S 42 USPQ2d 1001, 1997. In this case the starting material that has not been disclosed is any other transgenic non-human mammal embraced by the claims.

Given the lack of guidance provided by the instant specification for creation and use of other transgenic non-human mammals it would have required undue experimentation for one skilled in the art to make and/or use the claimed invention.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-54 and 66-76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20, 30, 42, and 66 are indefinite as written. The claims embrace a portion of an mRNA instability motif. The claims are indefinite because the neither claims nor the specification has provided a definition of a portion of an mRNA instability motif. Accordingly, it is not known what is meant by a portion of an mRNA instability motif. Appropriate correction is required. Claims 21-29, 31-41, 43-54 and 67-76 depend from claims 20, 30, 42, and 66 respectively.

Allowable Subject Matter

The following subject matter appears to be allowable:

A transgenic mouse whose genome comprises a modified nucleotide sequence, of the nucleotide sequence set forth in SEQ ID NO: 2, encoding a merozoite surface protein 1 (MSP-1) operably linked to a mammary gland specific promoter, wherein the modified nucleotide sequences of SEQ ID NO: 2 are as follows: a) a modified nucleotide sequence of SEQ ID NO: 2 such that the AT content is reduced to 50% or less by replacing wild-type codons with mammary gland preferred codons encoding the same amino acid as the replaced codon; b) a modified nucleotide sequence of SEQ ID NO: 2 such that the AT content is reduced to 50% or less by replacing wild-type codons with mammary gland preferred codons, wherein at least one glycosylation site of SEQ ID NO: 10 has been altered such that it is not functional, and wherein the altered glycosylation sites are at positions 182 and 263 of SEQ ID NO: 10; c) a modified nucleotide sequence of SEQ ID NO: 2 such that all the mRNA instability motifs have been eliminated by replacing wild-type codons with mammary gland preferred codons

encoding the same amino acid as the replaced codon; and d) a modified nucleotide sequence of SEQ ID NO: 2 such that all the mRNA instability motifs have been eliminated by replacing wild-type codons with mammary gland preferred codons encoding the same amino acid as the replaced codon, wherein at least one glycosylation site of SEQ ID NO: 10 has been altered such that it is not functional, and wherein the altered glycosylation sites are at positions 182 and 263 of SEQ ID NO: 10.

It is noted, if evidence can be provided which exemplifies another transgenic non-human mammal which expresses MSP-1 in milk, wherein MSP-1 is encoded to the extent of the described nucleotide sequences as set forth above then the enabled scope of the invention may be broadened to embrace transgenic non-human mammals.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

Art Unit 1632

PETER PARAS, JR.
PRIMARY EXAMINER